Message

From: Flowers, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1A4411C874D041B9A8BADFC32B91BD70-FLOWERS, LYNN]
Sent: 1/26/2012 12:16:26 PM
To: Clark, Becki [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a906e07f1cd143b9a3c2ddab813b8140-Clark, Becki]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Craig Johnson [Johnson.CraigLNDU@usepa.onmicrosoft.com]; Winner, Darrell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=860556f5cd0f4855839907bcc90b2c41-Winner, Darrell]; Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]; Debra Walsh [Walsh.DebraLNDU@usepa.onmicrosoft.com]; Perovich, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e3c19d7f4db41bfa2477aa27ad83945-Perovich, Gina]; Karen Hammerstrom [Hammerstrom.KarenLNDU@usepa.onmicrosoft.com]; Strong, Jamie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea753aafefb74c268550fe6a2c187838-Benedict, Jamie]; Deener, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]; Gwinn, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bdc5237a5c440a7b664518e23eb5647-Gwinn, Maureen]; Troyer, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=847b0020dd0e457e85f994a1ad64b26d-Troyer, Michael]; Birchfield, Norman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c910f2fd28414e819b6afe6dda525e9f-Birchfield, Norman]; Jones, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samantha]; Barone, Stan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4f8618acbba418da24c110f3123a2af-Barone, Stan]; Rieth, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00aac63cc995489188b8a449aaa18f5e-Rieth, Susan]; Berner, Ted [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1949c9653024d3cb4aa4c2bd69c4fde-Berner, Ted]; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]; Sanchez, Yolanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=473c34ae73994a4a8acafe6f03e0baeb-Sanchez, Yolanda]
CC: Elizabeth Erwin [Erwin.ElizabethLNDU@usepa.onmicrosoft.com]
Subject: Agencies Slated To Soon Release Study On Controversial Italian Cancer Data

Daily News

Agencies Slated To Soon Release Study On Controversial Italian Cancer Data

Posted: January 25, 2012

The National Toxicology Program (NTP) is expected to soon release its long-awaited review of carcinogenicity studies performed by a controversial Italian laboratory, studies relating to six of EPA's major chemical risk assessments, which the agency was forced to "hold" after an initial NTP review of one of the studies found inconsistencies.

Informed sources say that NTP is slated to soon release its final report on the validity of the Ramazzini Institute's data with one source indicating it may be released before the end of January.

If the final version of the report confirms preliminary findings, as is suspected, it could undermine the credibility of EPA's Integrated Risk Information System (IRIS) database -- which is used as the basis for a host of regulatory standards but is already facing multiple challenges from industry and congressional critics.

Based on NTP's summary of its review of the Italian lab's methanol study, EPA in June 2010 halted progress on four pending draft assessments that contained data from the Ramazzini Institute -- including those of methanol, the fuel additives methyl tertiary butyl ether (MTBE) and ethyl tert-butyl ether (ETBE), and the plastic ingredient acrylonitrile -- as well as existing assessments of vinyl chloride and 1,1 dichloroethylene (DCE), which were published on the IRIS website in 2000 and 2002 respectively.

NTP's summary, released in June 2010, raised questions about the results and methods of Ramazzini's studies on methanol's carcinogenicity and found a lower incidence of lymphoma or leukemia in Ramazzini's test rats exposed to methanol than Ramazzini scientists found. The summary report prompted EPA to delay the pending assessments and "hold" the two existing assessments.

Since then, a team of NTP pathologists traveled to the Italian labs in spring 2011 to perform a more extensive pathology working group review of several Ramazzini studies.

The results of this pathology working group are not expected to be a surprise, given the earlier review, an industry source says. The source adds that NTP Director Linda Birnbaum and EPA's research chief, Paul Anastas, are expected to meet shortly to discuss the report's release.

Another industry source says that EPA has indicated that it will "not change the report, but Anastas wants to meet with Birnbaum to agree on the interpretation before it is released." The source adds that because EPA partially funded the pathology working group, NTP provided EPA a copy of the report before releasing it publicly.

An EPA spokeswoman declined to comment, referring queries to NTP. An NTP spokeswoman did not return a request for comment.

Differing Lab Methods

The Ramazzini data has proven controversial largely because the lab's methods differ greatly from U.S. counterparts. EPA and other federal agencies tend to use lab rodent studies of specific duration -- generally two years -- to make decisions about chronic exposure to chemicals. They also often use pathogen-free strains of animals in labs with pathogen barriers, to avoid confounding infections.

The Ramazzini labs have a totally different perspective. The labs' science director Morando Soffritti told *Inside EPA* in a spring 2010 interview that his lab's study design -- eschewing pathogen-free animals and facilities and allowing the animals to die naturally -- better mimics human life.

American critics, however, argue that these decisions lead to confounding. In recent years, industry consultant George Cruzan and EPA scientists have authored several papers with competing explanations for an infection or lack of infection in the Ramazzini rats' lungs that could be confounding the studies' results. Some industry sources have even suggested that the location of the Ramazzini lab, housed in a fifteenth century castle, could exacerbate the lab animals' respiratory infections.

Since the controversy broke, the agency has taken some steps to advance what it can on the pending assessments. The agency is moving forward with its assessment of acrylonitrile. Last August, it released a draft assessment that avoided using Ramazzini data to calculate numerical its cancer risk estimates. "While these data are considered qualitatively as support for early-life susceptibility, EPA decided not to rely on these data for quantitative purposes," EPA said.

The agency's assessments of ETBE and DCE do not include cancer safety standards because the agency determined it did not have the necessary data to calculate these numbers. But the agency performed a weight of evidence analysis for declaring whether the chemicals are carcinogenic -- a determination that can result in consumer deselection -- including Ramazzini data.

EPA's draft assessment of MTBE has yet to be publicly released, so it is unknown to what extent it relies, or relied, on Ramazzini data.

But the agency told the Government Accounting Office that as of Sept. 30, the agency expected to complete the acrylonitrile and MTBE assessments and the non-cancer portion of the methanol assessment in fiscal year 2012, and its assessment of ETBE in FY2013. The cancer assessment of methanol's deadline remains "to be determined."

Observers expected in 2010 that assessments for methanol and vinyl chloride were expected to face lengthy delays because EPA relied on Ramazzini data to set numeric cancer risk levels for these two chemicals. --

Maria Hegstad (mhegstad@iwpnews.com This e-mail address is being protected from spambots. You need JavaScript enabled to view it)